NOV 1 2012

510(k) SUMMARY
as required by section 807.92(c)

Submitted by:	ThyssenKrupp Accessibility BV Van Utrechtweg 99 2921 LN Krimpen aan den Ijssel The Netherlands
Contact:	Arnold van der Heiden Mail: avanderheiden@tkacc.nl Tel: +31 180 530900 Fax: +31 180 530901
Date prepared:	10/05/2012
Trade Names:	LEVANT/ HOMEGLIDE
Common Device Name:	Battery Operated Stair Lift for Straight Stairs
Regulation Number	890.5150
Class	II
Product Code:	ILK
Submission	K121560
Predicate Devices:	Stair Lift BRUNO Independent Living Aids INC K113308, K033438 CFR 890.5150

Promotional Product Description

Levant/ HomeGlide is a stair lift for transport of one person up and down straight stairs. The system consist of a drive unit, a foldable seat, a foldable footrest and an aluminum rail that is fixed on the stairs. The system can be fixed on either sides of the stairs.

It is available standard with a manual swivel for easy getting on and off the seat. It comes with a padded seat. A hinged rail, a heavy duty drive and a intermediate park position are available as options.

The Comfort Option provides a premium positioned chair lift with extra options: straight or curved armrests, luxurious seat, fabric- vinyl- or leather upholstery, adjustable seat height, and a powered swivel.

The Outdoor Option provides a stair lift for outdoor use in both cold and warm climates. The Outdoor option is created by adding a waterproof control, a waterproof cover, coated electronics, coated switches, waterproof charging contacts and a step up transformer.

Intended Use

ThyssenKrupp Accessibilty's Battery Operated Stair Lift Levant is intended to mechanically transport one mobility impaired person in a fold-down seat, up and down straight stairs, indoors and outdoors.

Product Comparison Tables

Equivalent Technological Characteristics

	Bruno SRE-3000/ SRE-2000	ThyssenKrupp Accessibility Levant
Standards	ASME 18.1	ASME 18.1
Application	Straight stairs	Straight stairs
Rated Load	181 kg	146 kg
Passengers	1	1
Power	2 pieces 7AH 12 Battery	2 pieces 7AH 12 Battery
Charger	24VDC/ 2A	Ind:24VDC/ 1700 mA Outd: 6 VAC
Drive	Direct drive worm gear motor	Direct drive worm gear motor
Final Drive	8dp gear rack with spur gear	8dp gear rack with spur gear
Braking	Dynamic, worm gear, el/mech brake	Dynamic, worm gear, el/mech brake
Call & Send	IR	IR
Control	3-position momentary rocker switch	3-position momentary rocker switch
Supports	Anchored to stair thread	Anchored to stair thread
Angle	22 to 45 degrees, specials up to 52	28 to 53 degrees, heavy duty to 45
Speed	0.08 m/s	0.12 m/s
Track length	6.1 meters max	7.5 meters max
Construction Rail Indoors	Aluminum extrude rail	Anodized aluminum extrude rail
Safety devices	Multiple	Multiple
Footrest	Folding type	Folding type
Seat	Folding type	Folding type
Indoor use	Yes	Yes
Outdoor use	Yes	Yes

Non Equivalent Technological Characteristics

	Bruno SRE-3000/ SRE-2000	ThyssenKrupp Accessibility Levant
Temperature range Indoors	SRE-3000 (Bruno ref ILS-01024): not specified	Levant Standard + Comfort option: +5°C to +40°C (41°F to 104°F)
Temperature range Outdoors	SRE-2000 (Bruno ref ISO-404.88) -5°C to +50°C (25°F to 125°F)	Levant Outdoor option: -15°C to +60°C (5°F to 140°F)
Construction Rail Outdoors	Exterior grade powder coated steel rail	Anodized aluminum extrude rail
Construction Chair Outdoors	Stainless steel	ABS Synthetic material
Electrical enclosure	IPx3	IPx5

Product Comparison Discussion

Bruno's SRE-3000/ SRE-2000 and ThyssenKrupp Accessibility's Levant show substantial equivalence on most features and characteristics.

- Both products offer a higher rated load then the minimum requested by standards (EN 115kg, ASME 115kg). Bruno offers a maximum of 181 kg, where ThyssenKrupp Accessibility offers a maximum of 146 kg.
- Both product offer the possibility to install the rail at the maximum angle of inclination (EN 75°, ASME 45°). There is a small difference in the angle range, caused by differences in the design.
- Both products a travelling speed that is below the maximum allowed by standards (EN 0,15 m/s, ASME 0,4 m/s). Bruno specifies a speed of 0,08 m/s where ThyssenKrupp Accessibility offers a speed that is 50% higher.
- Standards do not specify a maximum track length. Bruno offers a maximum track length of 6,1 meters, where ThyssenKrupp Accessibility offers a maximum track length of 7,5 meters.
- Regarding the temperature range of the outdoor chair versions (Bruno SRE-2000 stainless steel, Levant Outdoor ABS Synthetic material) there is a difference. Where Bruno offers a minus temperature of 25°F, ThyssenKrupp Accessibility offers a minimum temperature of 5°F. Where Bruno offers a maximum temperature of 125°F, ThyssenKrupp Accessibility offers a maximum temperature of 140°F.

Small differences as listed above are subject to analysis of specific customer demands by the sales person.

Bruno's SRE-3000/ SRE-2000 and ThyssenKrupp Accessibility's Levant show less substantial equivalence on the features and characteristics listed below.

- ThyssenKrupp Accessibility offers anodized aluminium as rail material, where Bruno offers exterior grade coated steel. Although substantially different, both materials fulfil the requirements regarding the requested safety factors by the standards. The choice of material is subject to the taste of the end user.

- Bruno offers as protection against spraying water class IPx3, where IPx5 is offered by ThyssenKrupp Accessibility. IP55 is required by EN 81-40 referenced according IEC 60529. ASME does not specify a required IP level. The substantial difference can be explained by the fact that Levant is a European design, that has to meet EN 81-40. The difference in IP level can be subject of analysis of specific customer demands by the sales person.

Bruno's SRE-3000/ SRE-2000 and ThyssenKrupp Accessibility's Levant show minor differences in features and characteristics. From the point of view from ThyssenKrupp Technical Advisor, both products can be considered as substantially equal where the differences create more possibilities for adaption to specific customer demands, creating a bigger chance for mobility impaired persons to find suitable solution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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% Mr. Arnold Heiden
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NOV 1 2012

Re: K121560
Trade/Device Name: LEVANT
Regulation Number: 21 CFR 890.5150
Regulation Name: Powered patient transport
Regulatory Class: Class II
Product Code: ILK
Dated: October 24, 2012
Received: October 25, 2012

Dear Mr. Heiden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S
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Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121560

Device Name: LEVANT

Indications for Use:

ThyssenKrupp Accessibility's Battery Operated Stair Lift LEVANT is intended to mechanically transport one mobility impaired person in a fold-down seat, up and down straight stairs, indoors and outdoors.

Prescription Use NO (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use YES (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121560